MAY 1 4 2014

510(k) Summary

ArthroCare® Corporation
MultiFIX® S Knotless Fixation System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	ArthroCare Corporation
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Contact Person:	Laura Kasperowicz Sr. Manager, Regulatory Affairs Phone: 949-585-2406 Fax: 949-585-2401
Date Prepared:	March 7, 2014

Device Name

Proprietary Name:	MultiFIX® S Knotless Fixation System
Common Name:	Bone Anchor
Classification Name:	Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Product Code:	MBI
CFR Section:	21 CFR 888.3040

Predicate Device
MultiFIX® S Knotless Fixation System: K132590 (cleared September 17, 2013)

Description
The MultiFIX S Knotless Fixation System (MultiFIX S) is a laser marked PEEK implantable bone anchor with inserter handle designed for use in arthroscopic and orthopedic procedures. The MultiFIX S is a knotless fixation device, meaning that manually tying surgical knots is not necessary for the fixation of suture to tissue.

The MultiFIX S consists of two primary parts: a laser marked PEEK implantable bone anchor and an anchor inserter, which is preloaded with the anchor. The anchor inserter is a disposable tool. The entire product is packaged in a tray with a Tyvek® lid, and the finished product is sterilized by irradiation. Both the anchor and inserter are designed for single use only.

Intended Use/Indications For Use
The MultiFIX S Knotless Fixation Device is indicated for use in fixation of soft tissue to bone.
Examples of such procedures include:
Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis, and deltoid repair
Ankle: Lateral instability, medial instability, Achilles tendon repair/reconstruction, and midfoot reconstruction
Foot: Hallux valgus reconstruction
Elbow: Tennis elbow repair, biceps tendon reattachment

Knee: Extra-capsular repairs; reattachment of: medial collateral ligament, posterior oblique ligament or joint capsule closure to anterior proximal tibia; extra capsular reconstruction, ITB tenodesis; patellar ligament and tendon avulsions

Non-Clinical Data

Toxicological testing (Gas and Liquid Chromatography Mass Spectrometry and FTIR), biocompatibility testing (Cytoxicity) and bench testing (anchor pound-in) were performed. All toxicological and biocompatibility testing passed, demonstrating that the material is non-toxic, non-cytotoxic and equivalent to the predicate. Bench testing in bone foam analog confirmed that the laser marking has no impact on implant strength as the implant screw body was able to be successfully delivered sub-cortical at the end of deployment. The test results demonstrate that the proposed MultiFIX S meets its design, performance, and safety specifications. Based on the test results, the proposed device performs as intended and mechanical properties are substantially equivalent to the predicate device when used in accordance with labeling.

Clinical Data

No clinical or animal data are included in this submission.

Summary

All testing demonstrates that the proposed MultiFIX S performs as intended and has acceptable mechanical properties when used in accordance with its labeling.

As the intended use, operating principle, materials and technological characteristics are comparable to the predicate device, the proposed MultiFIX S Knotless Fixation System is substantially equivalent. The minor differences between the proposed MultiFIX S and predicate device do not raise any new questions of safety or effectiveness.

Comparison of Technological Characteristics		
Characteristics	**Predicate Device MultiFIX S (K132590)**	**Proposed Device MultiFIX S**
Intended Use	Fixation of soft tissue to bone	Same
Delivery Method	Arthroscopic and Limited Access	Same
How Supplied	Sterile	Same
Suture Material	No. 2 UHMWPE Suture	Same
Anchor Material	**Invibio PEEK Optima®**	**Invibio PEEK Optima®with laser marking to enhance anchor visualization during delivery**
Design Technology	Pound in Anchor with screw	Same
Bone Locking Mechanism	Interference Fit (threaded screw)	Same
Suture Locking Mechanism	Plug/Cylinder Compression	Same
# of Suture Legs	2, 3 or 4	Same

Comparison of Technological Characteristics		
Characteristics	**Predicate Device MultiFIX S (K132590)**	**Proposed Device MultiFIX S**
Diameter of Cortical Lock	5.5 mm & 6.5 mm	Same
Anchor Deployed Length	20 to 23 mm	Same
Device Length	291mm	Same
Sterilization Method	Irradiation	Same
Packaging	Sterile / Thermoform Tray with Tyvek Lid	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2014

ArthroCare® Corporation
Mr. Mitchell Dhority
Vice President, Regulatory Affairs
7000 West William Cannon Drive, Building One
Austin, Texas 78735

Re: K140604
Trade/Device Name: MultiFIX® S Knotless Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: April 18, 2014
Received: April 21, 2014

Dear Mr. Dhority:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140604

Device Name
MultiFIX® S Knotless Fixation System

Indications for Use *(Describe)*

The MultiFIX S is indicated for use in fixation of soft tissue to bone.

Examples of such procedures include:

Shoulder: Bankart Repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule shift/capsule-labral reconstruction, biceps tenodesis, and deltoid repair
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

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